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2 Summary of Safety and Effectiveness

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter:

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Name of the Device: MediPrime

Predicate Device: ProVision Diagnostic Workstation manufactured by *Algotec Systems Ltd.* (K954678 and K980648), and the RadWorks Viewing Station, manufactured by *Applicare* (K962699).

Description of the Device: The MediPrime is a multi-modality radiology reading station for viewing and processing radiological images. It is based on off-the shelf WindowsNT computers and a number of monitors (regular or high resolution) that comply with the accepted international standards for computer and monitor systems. The systems also comprises software developed and validated by *Algotec Systems Ltd.*

Intended Use: The system is intended for use by radiologists as an interactive tool for analyzing radiological data.

Comparison of Technological Characteristics: MediPrime and its predicate devices, the ProVision Diagnostic Workstation and the Applicare RadWorks Viewing Station, share many implementation and functional characteristics:

- Both MediPrime and ProVision systems share many common software components, such as Communication subsystems and Image Viewing algorithms. Most of the MediPrime software was originally developed for the ProVision workstation, and MediPrime is just the transfer of the ProVision capabilities from the Unix platform to the WindowsNT platform. Also, the major software components for both systems were written in the same language - C++.

- The MediPrime, ProVision and RadWorks systems provide standard image viewing tools such as: window/level, zoom, pan, annotations, etc. No image manipulation tools are implemented in MediPrime, that do not exist in either

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the ProVision or RadWorks.

- All systems can access any standard DICOM image server.

There are no new features affecting safety or effectiveness in MediPrime.
The difference between these systems raises no new issues of safety or effectiveness.

Sept. 13, 2000

Date

Dr. Menashe Benjamin, President

Signature, Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2000

Algotec Systems, Ltd.
c/o Eli M. Orbach
International Regulatory Consultants
P.O Box 6718
Efrat 90435
ISRAEL

Re: K002894
MediPrime (Radiology Reading Station)
Dated: September 13, 2000
Received: September 18, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Dr. Orbach:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

3 Indications For Use

Device Name: MediPrime K002894

Indication for Use:

MediPrime is a radiology reading station which provides storage, retrieval, printing, transmission, viewing and processing capabilities for radiological images.

The system is intended for use by radiologists as an interactive tool for analyzing radiological data.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Seyer

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002894

Prescription Use OR Over the Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)